IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

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| GAYNELL GRIER, et al., individually and on behalf of others similarly situated, | ) | |
| Plaintiffs, | ) | |
| v. | ) | Case No. 3:79-3107 |
| | ) | Judge Nixon |
| M.D. GOETZ, JR., Commissioner, Tennessee Department of Finance and Administration, et al., | ) | Class Action |
| Defendants, | ) | |
| and | ) | |
| TENNESSEE ASSOCIATION OF HEALTH MAINTENANCE ORGANIZATIONS, et al., | ) | |
| Defendants-Intervenors. | ) | |
| SANFORD BLOCH, MARK LEVINE, TIM JONES, and WILLIAM DUNCAN, and MARY KATHRYN DUNCAN, by their next friend, ROBERT DUNCAN, | ) | |
| Plaintiffs-Intervenors. | ) | |

**ORDER**

Upon request of the parties, the Court held a hearing in the above-styled action on Friday, July 29, 2005. During this hearing, Defendants informed the Court of their reaction to the Court's July 28, 2005 partial ruling on Defendants' Motion to Modify and/or Clarify the Consent Decree (Doc. No. 1246). The Defendants informed the Court that the Court's partial ruling enabled them to investigate methods to potentially postpone by ten days the reduction in pharmacy benefits for the non-pregnant Medically Needy adult population that will go into effect

on August 1, 2005. In order to provide the Defendants with sufficient time to implement their long-term reforms, which particularly affect the non-pregnant Medically Needy adults, the Court finds it necessary at this time to provide a complete ruling on Defendants' Motion to Modify and/or Clarify the Consent Decree (Doc. Nos. 1086, 1087), and the responses thereto. After consideration of the testimony adduced during the hearings that took place between June 29, 2005 and July 19, 2005; the parties Proposed Findings of Fact and Conclusions of Law (Doc. Nos. 1237, 1238, 1239, 1241, 1240); and upon hearing closing arguments on July 28, 2005, it is hereby **ORDERED** that Defendants' Motion to Modify and/or Clarify the Consent Decree (Doc. Nos. 1086, 1087) is **GRANTED in part** and **DENIED in part**.

The Court finds that there is significant change in the circumstances to warrant modification of the 2003 Revised Consent Decree (Modified). See Rufo v. Inmates of Suffolk County Jail, 502 U.S. 367 (1992); Fed. R. Civ. P. 60(b). The Court also finds that certain modifications are suitably tailored to the changed circumstances, while others are not. Id. Accordingly, the Court hereby orders that:

(i) Defendants' Request (a) regarding the implementation of all reforms approved by the Centers for Medicare and Medicaid Services ("CMS"), is **GRANTED in part** and **DENIED in part**. Pursuant to Fed. R. Civ. P. 60(b) and the governing case law, the Court cannot revise the 2003 Revised Consent Decree (Modified) unless the proposed modifications are suitably tailored to rectify the circumstances that warrant modification. See Rufo v. Inmates of Suffolk County Jail, 502 U.S. 367 (1992); Fed. R. Civ. P. 60(b). Similarly, the proposed modifications must fall within constitutional requirements. Id. The Court cannot conduct this analysis on future reforms that the State has not yet articulated to this Court. Accordingly, the State may

implement the reforms already approved by CMS in its letters to the State dated March 24, 2005 and June 8, 2005 subject to this Court's ruling as set forth below. Defendants' Request (a) regarding implementation of future reforms not yet approved by CMS is **DENIED**;

(ii) Defendants' Request (b) regarding prior authorization is **GRANTED in part** and **DENIED in part**. The State may require prior authorization by the TennCare Bureau as a condition of coverage for any drug or drug class so designated by the State. The Court finds that categorical denial of a claim for reimbursement for a drug for which prior authorization is required but has not been obtained is not suitably tailored to the circumstances. Accordingly, the State may not deny reimbursement for a 72-hour emergency supply of a drug for which prior authorization is required but has not been obtained in accordance with the Court's ruling in subparagraph (vii) of this Order. Similarly, the State may not categorically deny a claim for reimbursement from an enrollee. Upon receiving an enrollee's request for reimbursement for a drug for which prior authorization is required but has not been obtained, the State must conduct the same prior authorization process or analysis it would have conducted prior to the dispensing of the drug. In the event the prior authorization would have been granted, the enrollee shall be reimbursed. In the event the prior authorization would have been denied, the enrollee's request for reimbursement shall be denied, at which point the enrollee may appeal the State's decision to deny authorization of the drug consistent with subparagraph (iv) of this Order. This ruling does not extend to claims for reimbursement by providers and pharmacists, and the State may deny any claim for reimbursement by providers and pharmacists for a drug for which prior authorization is required but has not been obtained;

(iii) Defendants' Request (c) regarding the five prescription per month limit is

**GRANTED** with the Court's recommendation and expectation that the State will implement a "soft" five prescription per month limit, as reflected by the State's representation during closing argument on July 28, 2005 and after creating and obtaining CMS approval for an appropriate "soft" limit policy;

(iv) Defendants' Request (d) regarding appeals of denials of authorization for a drug is **GRANTED in part** and **DENIED in part**. Accordingly, the Court hereby orders that:

(1) The State may, when a request for prior authorization of a drug is denied, issue through its Pharmacy Benefit Manager ("PBM") a notice informing the enrollee of the basis for the denial, and that notice may be after the service has been denied.

(2) If the enrollee appeals the denial of prior authorization or coverage, the State will have no obligation to pay for the service during the pendency of any appeal, subject to the following exceptions:

(A) The State shall comply with the 72-hour emergency supply requirements of Paragraph C(14)(a) – (c), as revised by subparagraph (vii) of this Order; the enrollee is entitled under those provisions to a single 72-hour emergency supply while the appeal is pending; or,

(B) The drug in question has been prescribed on an ongoing basis or with no specific ending date (e.g., insulin for the treatment of diabetes), in which case the State or its contractor shall comply with Paragraph C(2)(c) and C(8) of the 2003 Revised Consent Decree (Modified); or,

(C) The enrollee ultimately prevails on the appeal and is found to have been eligible to have received the services, in which case the State or its contractor shall make

corrective payments, retroactive to the date that the incorrect denial of coverage occurred, as required by 42 C.F.R. § 431.246 and Paragraph C(13) of the 2003 Revised Consent Decree (Modified), as revised by subparagraph (xv) of this Order.

(3) The State action from which an appeal may be taken is the State's denial of requested prior authorization. Such action is included within the definition of an "adverse action" giving rise to the right to appeal under Paragraph B(5) of the 2003 Revised Consent Decree (Modified). Insofar as the State's motion requests a modification to limit appeals to the State's denial of requested prior authorization, it is **DENIED**.

(4) A valid appeal may be taken where no prior authorization has been sought for a drug requiring such authorization in order to be treated as a covered service (and therefore no prior authorization request has been denied).

(5) The State may dismiss without a hearing any appeal of a denial of prior authorization that does not raise a valid factual dispute. See Rosen, et al., v. Goetz, 410 F.3d 919 (6th Cir. 2005);

(v) Defendants' Request (e) regarding the content of a drug formulary and designation of drugs available without prior authorization is **GRANTED**;

(vi) Defendants' Request (f) regarding categorical exclusion of coverage for over-the-counter drugs is **GRANTED** with the Court's recommendation that over-the-counter drugs be excluded on a "soft" basis consistent with this Court's ruling in subparagraph (iii) above;

(vii) Defendants' Request (g) regarding the 72-hour drug supply for drugs requiring prior authorization for which such authorization has not been obtained is **GRANTED** with the Court's recommendation that the prior authorization policy be phased in to allow initially a 72-

hour *interim* supply of a prescription drug for which no prior authorization has been obtained, until such time that pharmacists have been provided appropriate guidelines and have received training in how to determine an *emergency* situation, as defined by the State, at which time the 72-hour supply will be limited to *emergency* situations;

(viii) Defendants' Request (h) regarding benefit limits is **GRANTED in part** and **DENIED in part**. Accordingly, the Court hereby orders that:

(1) When the State imposes benefit limits capping the number of in-patient hospital days per year, physician services per year, outpatient facility services per year, laboratory and x-ray services per year, inpatient and outpatient substance abuse services over the course of the enrollee's lifetime, and/or prescriptions per month that will be covered by TennCare, the State may deny any claim for services or reimbursement for services whenever such service would exceed a benefit limit imposed by the State. The Court recommends that the State implement a "soft" benefit limit consistent with this Court's ruling in subparagraph (iii).

(2) When a claim for service or reimbursement is denied by the State or a managed care contractor ("MCC") because the enrollee has reached the benefit limit, the State must issue a notice informing the enrollee of the basis for the denial at the time the claim is denied (which may be after the service has been denied by a provider) .

(3) The State need not provide notice that an enrollee is approaching or has exceeded his benefit limit.

(4) A provider's refusal to render a requested service because the enrollee has reached a benefit limit constitutes action by the State, and the State shall provide notice in those

circumstances. See Tennessee Assoc. of Health Maintenance Orgs., Inc. v. Grier, 262 F.3d 559 (6th Cir 2001). This ruling does not preclude the State from creating a standard, preprinted notice for distribution by providers in such situations.

(5) If the enrollee appeals the denial of coverage, the State may refuse to pay for the service while the appeal is pending; provided, however, that if the enrollee ultimately prevails on the appeal, the State or its contractor must take corrective action, as required by 42 C.F.R. § 431.246.

(6) The State may dismiss without a hearing any appeal of a denial based upon a benefit limit that does not raise a valid factual dispute. See Rosen, et al., v. Goetz, 410 F.3d 919 (6th Cir. 2005);

(ix) Defendants' Request (i) regarding co-pays is **GRANTED in part** and **DENIED in part**. Accordingly, the Court hereby orders that:

(1) The State may impose and/or increase the co-pays charged for any TennCare service.

(2) The State may not deny any claim for services for which the co-pay has not been paid.

(3) The State may dismiss without a hearing any appeal of a denial for refusal to pay the co-pay that does not raise a valid factual dispute.

(4) A provider's refusal to provide a requested service because the enrollee did not pay the co-pay constitutes action by the State, and the State shall provide notice in those circumstances. See Tennessee Assoc. of Health Maintenance Orgs., Inc. v. Grier, 262 F.3d 559

(6th Cir 2001). This ruling does not preclude the State from creating a standard, preprinted notice for distribution by providers in such situations;

(x) Defendants' Request (j) regarding appeals of service denials that also raise eligibility category challenges is **GRANTED in part** and **DENIED in part**. The State may refuse to consider, as a ground for an appeal of a service denial, challenges to an enrollee's eligibility category that an enrollee had the opportunity to raise previously unless the enrollee can show excusable neglect for not previously raising the eligibility category challenge. The State may implement an administrative process to determine whether there is excusable neglect preventing a previous challenge to an eligibility category.

(xi) Defendants' Request (k) regarding appeals initiated by an enrollee without a prescription or service is **DENIED**. Notwithstanding this ruling, Paragraph C(10) does not prevent the State from creating an administrative grievance or other informal process to address requests by enrollees without a prescription or a service, including, but not limited to, network access requests. Paragraph C(10), in accordance with 42 C.F.R. § 431.220(a), requires the State to permit an appeal if an enrollee's request through any administrative grievance or informal process the State implements is not acted upon with reasonable promptness.

(xii) Defendants' Request (l) is **GRANTED in part** and **DENIED in part** such that the State may rely upon all relevant information, not just the enrollees' medical records in determining TennCare coverage of medical services and in considering and deciding medical appeals. Defendants' request to delete Paragraph C(7) of the 2003 Revised Consent Decree (Modified) is **DENIED**, but the first sentence of Paragraph C(7)(b) may be revised. The State, upon consultation with the other parties to this action, shall submit its proposal for approval of

such modification to this Court at a time to be determined by this Court subsequent to the issuance of the Memorandum Order;

(xiii) Defendants' Request (m) is **GRANTED**. See Rosen, et al., v. Goetz, 410 F.3d 919 (6th Cir. 2005);

(xiv) Defendants' Request (n) is **GRANTED** subject to subparagraph (xii) of this Order;

(xv) Defendants' Request (o) to modify Paragraph C(13) of the 2003 Revised Consent Decree (Modified) is **GRANTED**. Notwithstanding this ruling, the State must comply with 42 C.F.R. § 431.246 requiring prompt corrective action in the event of a decision favorable to the enrollee at any stage of the appeals process and the State may not await the conclusion of its appeal in order to take corrective action;

(xvi) Defendants' Request (p) to modify Paragraph C(16) regarding the time limitations for filing and resolving medical appeals and Paragraph B(14) setting forth the standard for expedited appeals is **GRANTED in part** and **DENIED in part**.

(1) The State may modify the time limitations in Paragraph C(16) to ensure sufficient time to obtain the enrollees' medical records. Notwithstanding this ruling, the State may not modify the time limitations to exceed the requirements of 42 C.F.R. § 431.244(f). The State, upon consultation with the other parties to this action, shall submit its proposal for approval of such modification to this Court at a time to be determined by this Court subsequent to the issuance of the Memorandum Order.

(2) The State may not modify Paragraph B(14) setting forth the standard for

expedited appeals;

(xvii) Defendants' Request (p) regarding remedying any defect in a required notice or statement of reasons or legal authorities is **GRANTED**;

(xviii) Defendants' Request (r) regarding their ability to evaluate claims for service in accordance with the definition of medical necessity established by State law (including regulations issued pursuant to the promulgating statute) is **GRANTED**. Paragraphs C(4) and C(7) (as revised by subparagraph (xii) of this Order) of the 2003 Revised Consent Decree (Modified) are not inconsistent with the definition of medical necessity, as they both require the State to consider the enrollees medical records and make an individualized decision;

(xix) Defendants' Request (s) regarding reasonable geographical and/or clinical hardship criteria to determine transfers between MCCs outside of defined open enrollment periods is **GRANTED** subject to paragraph D(4) of the 2003 Revised Consent Decree (Modified);

(xx) Defendants' Request (t) is **DENIED**.

This ruling will be followed by a Memorandum Order explaining the Court's reasoning.

It is so ORDERED.

Entered this the 29th day of July, 2005.

JOHN T. NIXON, SENIOR JUDGE
UNITED STATES DISTRICT COURT